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7 Attorneys for Defendant
8 RAMESH “SUNNY” BALWANI

9 UNITED STATES DISTRICT COURT
10 NORTHERN DISTRICT OF CALIFORNIA
11 SAN JOSE DIVISION

12 UNITED STATES OF AMERICA,

13 Plaintiff,

14 v.

15 RAMESH “SUNNY” BALWANI,

16 Defendant.

Case No. CR-18-00258-EJD

**RAMESH “SUNNY” BALWANI’S
MOTION TO ADMIT TRIAL
EXHIBIT 20683**

Date: May 17, 2022

Time: 8:30 a.m.

CTRM.: 4, 5th Floor

Hon. Edward J. Davila

MOTION TO ADMIT TRIAL EXHIBIT 20683

PLEASE TAKE NOTICE that on May 17, 2022, at 8:30 a.m. or on such other date and time as the Court may order, in Courtroom 4 of the above-captioned Court, located at 280 South First Street, San Jose, CA 95113, before the Honorable Edward J. Davila, Defendant Ramesh “Sunny” Balwani will and hereby does respectfully move the Court pursuant to Federal Rules of Evidence 401, 403, and 803 to admit Trial Exhibit 20683. The Motion is based on the below Memorandum of Points and Authorities, the concurrently filed Declaration of Jeffrey B. Coopersmith and attached exhibits, the record in this case, and any other matters that the Court deems appropriate.

DATED: May 16, 2022

Respectfully submitted,

ORRICK HERRINGTON & SUTCLIFFE LLP

By: /s/ Jeffrey B. Coopersmith
Jeffrey B. Coopersmith

Attorney for Defendant
RAMESH “SUNNY” BALWANI

MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION

At the trial of co-defendant Elizabeth Holmes, over the government’s objections, the Court admitted a portion of a report published by the Centers for Disease Control (CDC) that explains the multi-step process for HIV testing. *See* 11/18/2021 Holmes Trial Tr. at 6824–27. Anticipating similar objections, Mr. Balwani moves to admit the same evidence: page 9 of Trial Exhibit 20683, which is publicly available on the CDC website.¹ *See* Declaration of Jeffrey B. Coopersmith, Ex. 1 at 9 (TX 20683). The exhibit is a relevant public record, it is self-authenticating, and it will not present occasion for expert testimony. The Court should apply its ruling from the Holmes trial and admit the exhibit.

II. FACTUAL BACKGROUND

The patient-witness known as “E.T.” went to Theranos in 2015 for an HIV test. *See generally* 11/17/2021 Holmes Trial Tr. at 6750–57. Theranos proceeded according to the CDC’s algorithm for HIV testing, which includes several component assays.²

First, Theranos performed an HIV screener test, i.e., an immunoassay “that detects HIV-1 and HIV-2 antibodies and HIV-1 p24 antigen to screen for established infection with HIV-1 or HIV-2 and for acute HIV-1 infection.” Ex. 1 at 9 (CDC Report). E.T.’s sample was reactive for antibodies and/or antigen on the HIV screener. *See* Coopersmith Decl. Ex. 2 at 2 (TX 5483) (Theranos Report); 11/17/2021 Holmes Trial Tr. at 6755–56.

Then, Theranos proceeded to the second step of the CDC algorithm, which is an “immunoassay that differentiates HIV-1 antibodies from HIV-2 antibodies.” Ex. 1 at 9 (CDC

¹ <https://stacks.cdc.gov/view/cdc/23447>. This motion concerns page 9 according to the exhibit’s pagination, which corresponds to page 7 of the CDC document. At the Holmes trial, the same exhibit was referred to as Trial Exhibit 12692.

² Theranos ran E.T.’s HIV test on non-Theranos technology. *See* Dkt. 1156 at 4–5. Mr. Balwani maintains that all evidence pertaining to E.T. should be excluded for the reasons articulated in his motion in limine. *Id.* at 4–6.

Report). E.T.’s sample tested negative for both HIV-1 antibodies and HIV-2 antibodies. Ex. 2 at 2 (Theranos Report); 11/17/2021 Holmes Trial Tr. at 6756.

Finally, Theranos proceeded to the third step of the CDC algorithm, an “HIV-1 nucleic acid test.” Ex. 1 at 9 (CDC Report). E.T.’s sample tested negative for HIV-1 nucleic acid. Ex. 2 at 2–3 (Theranos Report); 11/17/2021 Holmes Trial Tr. at 6756.

As the CDC algorithm provides—and as the Theranos report explained to E.T. at the time—this combination of results meant that “HIV antibodies were not confirmed and HIV-1 RNA [nucleic acid] was not detected. No laboratory evidence of HIV-1 infection. Follow-up testing for HIV-2 should be performed if clinically indicated.”³ Ex. 2 at 3 (Theranos Report); *see also* Ex. 1 at 9 (CDC Report); 11/17/2021 Holmes Trial Tr. at 6757. These second- and third-step assays are designed to confirm whether the patient is in fact HIV-positive, *see* Ex. 1 at 7–11 (CDC Report), and Theranos did exactly that, Ex. 2 at 2–3 (Theranos Report).

III. ARGUMENT

The CDC report is an admissible public record that provides important context for the jury’s understanding of Count 10, the charge relating to patient E.T. It is a relevant and self-authenticating public record, and it should be admitted.

Trial Exhibit 20683 is relevant because it offers the necessary context for understanding the series of HIV-related assays administered on E.T.’s sample—context that will otherwise be missing from this trial. *See* Fed. R. Evid. 401. The CDC report explains the iterative nature of HIV testing, which is designed to confirm and identify the virus at the conclusion of a multistep process. *See* Ex. 1 at 9 (CDC Report). Without some evidence explaining the nature of these assays—first, a screener; second, confirmatory tests—jurors are likely to be confused by E.T.’s testimony, prejudicing Mr. Balwani on an issue central to one of the charged counts. *See* Fed. R.

³ HIV-2 infections are exceedingly rare in the United States. *See, e.g.*, TX 20683 at 26.

1 Evid. 403.

2 The government did not object on hearsay grounds to Trial Exhibit 20683 at the Holmes
3 trial, and for good reason: it is an admissible public record. It is a CDC report that offers
4 “recommendations for HIV testing by laboratories in the United States” based on the CDC’s
5 investigation into the available tests, “scientific evidence, laboratory experience, and expert
6 opinion collected from 2007 through December 2013.” Ex. 1 at 7. It therefore falls within the
7 scope of the hearsay exception for a “record or statement of a public office” that “sets out” “the
8 office’s activities” or “factual findings from a legally authorized investigation.” Fed. R.
9 Evid. 803(8)(A)(i), (iii). Courts routinely admit similar recommendations and reports from federal
10 agencies under Rule 803(8). *See, e.g., Allen v. Hylands Inc.*, No. CV 12-1150, 2015 WL
11 12720304, at *13 (C.D. Cal. Aug. 20, 2015) (denying motion to exclude statements from
12 Department of Health and Human Services website), *aff’d in part & rev’d in part on other*
13 *grounds*, 773 F. App’x 870 (9th Cir. 2019).⁴

14 No foundation is required to admit a public record, because “the public records exception
15 is one of the few hearsay exceptions that does not require a foundation.” *United States v. Loyola-*
16 *Dominguez*, 125 F.3d 1315, 1318 (9th Cir. 1997). And because the CDC report is a “publication
17 purporting to be issued by a public authority,” it is self-authenticating. Fed. R. Evid. 902(5). As
18 the Court explained in *Garcia v. Folks*, “[w]hen Evidence Rules 902(5) and 803(8) are combined,
19 ‘official publications posted on government agency websites should be admitted into evidence
20 easily.’” No. 2:14-cv-2378, 2019 WL 1452904, at *6 (E.D. Cal. Apr. 2, 2019) (quoting *Lorraine*

21
22 ⁴ *See also Frye v. CSV Transp. Inc.*, No. 2:14-cv-11996, 2018 WL 3968590, at *2 (E.D. Mich.
23 Aug. 19, 2018) (finding FDA medication guide admissible under Rule 803(8)), *aff’d*, 933 F.3d
24 591 (6th Cir. 2019); *Guthrie v. Ball*, No. 1:11-cv-333-SKL, 2014 WL 5314576, at *6 (E.D. Tenn.
Oct. 17, 2014) (denying motion to exclude FDA healthcare alert under Rule 803(8)); *Bode v.*
Parkview Health Sys., Inc., No. 1:07-CV-324, 2009 WL 790199, at *2 (N.D. Ind. Mar. 23, 2009)
(denying motion to strike CDC report under Rule 803(3)).

1 v. *Markel Am. Ins.*, 241 F.R.D. 534, 551 (D. Md. 2007)).

2 The government objected to Trial Exhibit 20683 under Rule 702 at the Holmes trial, and
3 the Court correctly overruled that objection. 11/18/2021 Holmes Trial Tr. at 6826–27. Nothing in
4 E.T.’s testimony about the exhibit required her to deploy “scientific, technical, or other
5 specialized knowledge,” and Mr. Balwani’s counsel intends to stay within those same lay-witness
6 bounds. Fed. R. Evid. 702(a).

7 Trial Exhibit 20683 is a relevant, self-authenticating public record that is necessary to
8 avoid juror confusion, and the government’s objections to it in the Holmes trial were meritless.
9 The Court should apply its prior ruling to this trial and admit page 9 of Trial Exhibit 20683.

10 **IV. CONCLUSION**

11 For all the above reasons, Mr. Balwani asks the Court to grant this motion.

12 DATED: May 16, 2022

Respectfully submitted,

13 ORRICK HERRINGTON & SUTCLIFFE LLP

14 By: /s/ Jeffrey B. Coopersmith
Jeffrey B. Coopersmith

15 Attorney for Defendant
16 RAMESH “SUNNY” BALWANI
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